

AS Arsenic Science

Task Force

January 23, 2018

Teresa Fryberger, Ph.D.
Director
Board on Environmental Studies and Toxicology
Committee Engineering and Medicine
National Academies of Science
210 Constitution Avenue NW
Washington, DC 20418

RE: Review of Advances Made to the IRIS Process: A Workshop

Dear Director Fryberger:

The Arsenic Science Task Force¹ (ASTF) writes to express its concern with the approach the Board on Environmental Studies and Toxicology (BEST) has chosen to take in its upcoming review of the EPA Integrated Risk Information System (IRIS) program. Specifically, the title of the Workshop assumes the conclusion EPA would like the Board to reach and is therefore biased on its face. The statement of task is unacceptably narrow, being based solely on presentations offered by EPA staff, thus ensuring the discussions will be focused on the recently-appointed IRIS program management's advocacy of its internal view that the process has been improved during its brief tenure.

A more robust and objective statement of task is both necessary and appropriate to equip the Committee to assess the extent to which EPA's proposed procedural changes to IRIS have resulted in a program capable of gathering, assessing, and integrating the scientific literature with respect to chemical assessments in a way that is (i) transparent to the public; (ii) timely; (iii) balanced; and (iv) reflective of the

¹ ASTF is an informal organization of arsenic stakeholders whose objective is to ensure a full, fair, and objective integration of the relevant scientific evidence is carried out in the development of EPA's forthcoming Integrated Risk Information System (IRIS) assessment of inorganic arsenic.

best current scientific methodologies. Similarly, the meeting should be held in a format that allows stakeholders in the IRIS process to provide views in a more comprehensive manner than allowed by the brief public comment slots. Only in this way can the Board obtain the balanced information on the current status of the program that it needs to reach a well-informed decision.

Based on the Workshop agenda, we expect the upcoming workshop to be distressingly similar to the review by the EPA Science Advisory Board last fall, which resulted in an orchestrated presentation of the claims by the IRIS staff that the documented failures of the program have been recently fixed.

One would have expected the independent National Academies to take a radically different approach. Instead of a one-sided statement of task focused on presentations by EPA staff, an agenda structured around the documented recommendations for improvements to IRIS with EPA staff providing responses would have provided for a more objective discussion. While the published agenda seems to provide ample opportunities for stakeholder comments throughout the course of the workshop, it has been clarified that each person can make comments only once during the two-day Workshop and for a very short period of time. Even if those truncated opportunities were increased, the workshop's parameters still fall far short of a rigorous review.

ASTF does not believe that the Committee, when constrained by the current statement of task and meeting format, can fully evaluate whether EPA has adequately addressed the numerous substantive and procedural criticisms directed at the IRIS program in prior NAS reports, including the 2014 NAS review of the IRIS process (2014 NAS Report) and the 2011 NAS review of the draft IRIS Assessment of Formaldehyde (2011 NAS Formaldehyde Report).

ASTF has been actively engaged in the IRIS assessment process more than 10 years as the development of the revised draft of inorganic arsenic has proceeded. We have advocated for significant IRIS improvements to ensure that it is based on objectivity, transparency, and scientific accuracy. We have conducted literature searches to identify scientific gaps and have performed research on arsenic to improve the scientific database and provide a stronger basis for the risk

assessment process. The results of our research have been published in peer-reviewed journals and these publications were submitted to EPA for consideration in the development of the arsenic assessment. The ASTF, and other stakeholders, are closely familiar with the IRIS program's promises to make improvements. For example, while IRIS program officials presented their approach to systematic review at a workshop in 2015, we were concerned that their application of systematic review failed to incorporate mode of action methodologies, which is a fatal flaw.

We continue to be alarmed by the inconsistencies in the IRIS program and bias in the selection and evaluation of scientific studies relevant to the assessment of inorganic arsenic. Our review of the list of studies identified by IRIS as those on which they will rely, as documented in the Health and Environmental Research Online (HERO) database, revealed the exclusion of highly relevant studies, and the inclusion of others that had no relevance.

Finally, the ASTF is concerned the 9-month timeframe for completion of the review is artificially brief and will not permit a thorough review of the IRIS risk assessment methods. The Committee should extend the 9-month timeframe to ensure that it has sufficient time to effectively evaluate the IRIS program changes and to solicit additional stakeholder engagement and input. We strongly encourage an NAS process that allows for a full review of the IRIS risk assessment methods.

We urge the Committee to significantly revise the statement of task and to change the meeting format to ensure the many documented recommendations for improvements in the IRIS program are being thoroughly examined, that there are sufficient opportunities for meaningful stakeholder involvement, and that a sufficient amount of time is allotted for the Committee to conduct this critical review.

Sincerely,

A handwritten signature in dark ink, appearing to read "W. J. Adams". The signature is fluid and cursive, with the first name "W. J." and the last name "Adams" clearly distinguishable.

William J. Adams, Ph.D., SETAC Fellow
Chair

cc: The Honorable Scott Pruitt,
Administrator
Environmental Protection Agency

Jennifer Orme-Zavaleta
Principal Deputy Assistant Administrator
Office of Research & Development
Environmental Protection Agency